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Table with 5 columns: APPLICATION NO., FILING DATE, FIRST NAMED INVENTOR, ATTORNEY DOCKET NO., CONFIRMATION NO.
09/529,575 04/14/2000 FRANCIS JAMES ROURKE 7042-R 9622

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EXAMINER

ANDERSON, CATHARINE L

ART UNIT PAPER NUMBER

3761

MAIL DATE DELIVERY MODE

07/08/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

**Office Action Summary**

<b>Application No.</b> 09/529,575	<b>Applicant(s)</b> ROURKE ET AL.	
<b>Examiner</b> Lynne Anderson	<b>Art Unit</b> 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1)  Responsive to communication(s) filed on 20 December 2007.
- 2a)  This action is **FINAL**.
- 2b)  This action is non-final.
- 3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4)  Claim(s) 31,32,36,42-44,46,48,52 and 53 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5)  Claim(s) \_\_\_\_\_ is/are allowed.
- 6)  Claim(s) 31,32,36,42-44,46,48,52 and 53 is/are rejected.
- 7)  Claim(s) \_\_\_\_\_ is/are objected to.
- 8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9)  The specification is objected to by the Examiner.
- 10)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All   b)  Some \*   c)  None of:  
1.  Certified copies of the priority documents have been received.  
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1)  Notice of References Cited (PTO-892)
- 2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3)  Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4)  Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 5)  Notice of Informal Patent Application
- 6)  Other: \_\_\_\_\_.

## DETAILED ACTION

### *Response to Arguments*

1. Applicant's arguments filed 20 December 2007 have been fully considered but they are not persuasive.
2. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).
3. In response to applicant's argument that Roe fails to teach enzyme inhibitors, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). In the present case, Roe discloses a lotion having an antibacterial component. Caldwell teaches the use of pentamidine as an antibacterial. Therefore it would be obvious to provide the antibacterial, pentamidine, to the lotion of Roe. Since pentamidine inherently functions as an enzyme inhibitor, the product of Roe, as modified by Caldwell, fulfills the limitations of the present claims.
4. In response to the applicant's argument that Caldwell fails to disclose a topsheet for an absorbent article, it is noted that Caldwell is relied upon for the teaching of pentamidine as a suitable antibacterial agent for use in an absorbent article, not for the topsheet material itself.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 31, 32, 36, 42-44, 46, 48, and 52-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roe (5,607,760) in view of Cadwell (5,874,164).

6. With respect to claims 31, 32, 36, 42 and 44, Roe discloses all aspects of the claimed invention with the exception of the protease inhibitor being pentamidine and present in the amount of 0.0001-30% by weight. Roe discloses a disposable wearable article comprising a liquid permeable topsheet 520, a liquid impervious backsheet 530, and an absorbent core 540. The topsheet comprises a delivery system in the form of a lotion, as disclosed in column 3, lines 3-5. The lotion includes an antibacterial, as disclosed in column 23, lines 24-31.

7. Cadwell teaches the application of an antibacterial protease inhibitor, pentamidine, to an absorbent article, as described in column 55, lines 16-19 and 28. It would have been obvious to one of ordinary skill in the art at the time of invention to provide the lotion of Roe with pentamidine, as taught by Cadwell, to yield the predictable result of providing the lotion with antimicrobial activity.

8. The lotion of Roe is applied to the topsheet in an amount that will impart the desired therapeutic benefits of the lotion without saturating the topsheet, as disclosed in column 24, lines 1-12. It would therefore have been obvious to one of ordinary skill in

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the art at the time of invention to apply the lotion in an amount such that the protease inhibitor would be present in the article in a range of about 0.0001% to about 30% by weight because there would have been a reasonable expectation of success that such an amount would provide a therapeutic benefit without requiring so much lotion that the topsheet would be saturated.

9. The  $IC_{50}$  is defined in the instant specification on page 7 as being dependant on the concentration of protease inhibitor and the rate of substrate cleavage of the protease inhibitor. The rate of substrate cleavage is dependent on the individual protease inhibitor, and pentamidine is disclosed in the specification as being a suitable protease inhibitor. Therefore, pentamidine, when present in the claimed concentration, inherently has an  $IC_{50}$  of about 500  $\mu$ M or less, no more than 100  $\mu$ M, and as a result is capable of producing at least a 10% reduction in substrate hydrolysis by a protease.

10. With respect to claim 43, the lotion is transferable to the skin of a wearer, as disclosed in column 25, lines 25-27.

11. With respect to claim 46, the deliver system contains the protease inhibitor as molecules, or particles, as disclosed by Cadwell in column 55, line 37.

12. With respect to claim 48, the lotion is applied to the wearer-contacting surface of the topsheet, as disclosed in column 25, lines 25-27.

13. With respect to claims 52 and 53, the lotion is applied in a plurality of stripes with a region of the topsheet not containing lotion, as shown in figure 2.

***Conclusion***

14. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lynne Anderson whose telephone number is (571)272-4932. The examiner can normally be reached on Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/L. A./

Examiner, Art Unit 3761

/Tatyana Zalukaeva/

Supervisory Patent Examiner, Art Unit 3761